4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910-0769--Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to FDA's Center for Devices and Radiological Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form), by email, or by regular mail.

FDA published a 60-day notice for public comment in the *Federal Register* of June 12, 2023 (88 FR 38061) and received comments. While one comment appeared to question the purpose of the information collection, another comment supported FDA activities regarding the

reporting of information covered by the collection. No comment suggested that we revise our burden estimate.

We also received suggestions on how our submission form might be improved. In response to this comment, we are revising the submission form using asterisks to more clearly indicate which fields are required for submission versus non-required fields. The form also has been updated to allow submission of the company's website.

Similarly, one comment noted that current procedures do not allow for complete anonymity when submitting allegations of regulatory misconduct to FDA. The comment suggests changing the submission process to allow submission of attachments to the form, rather than via separate email. While we have not made changes regarding the submission process at this time, we appreciate these suggestions and continue to consider enhancements and updates to our systems as our limited resources permit. We recognize that confidentiality is an important concern. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

Finally, one comment expressed concern regarding verification by FDA of the accuracy and validity of the information (allegations) submitted. Allegations of regulatory misconduct related to medical devices are reviewed by CDRH. CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients, and takes responsive action accordingly. We note, however, that subsequent questions or inquiry intended to clarify information submitted is not considered a collection of information under the PRA (see 5 CFR 1320.3(h)(9)) subject to OMB review and approval. To learn more about CDRH's process for handling allegations, please visit: https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Electronic submission of voluntary allegations to CDRH	2,500	1	2,500	0.25 (15 minutes)	625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We recently consolidated the intake of allegations across CDRH Offices. This has improved our estimate and we have adjusted the number of responses accordingly. The number of responses is based on the voluntary allegations received by CDRH in 2022. The adjusted estimated burden for the information collection reflects an increase of 900 responses and a corresponding increase of 225 hours.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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